NIH Genomic Data Sharing:

Managing Variables & Risks in an Evolving Landscape

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The NIH GWAS Data Sharing Policy

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

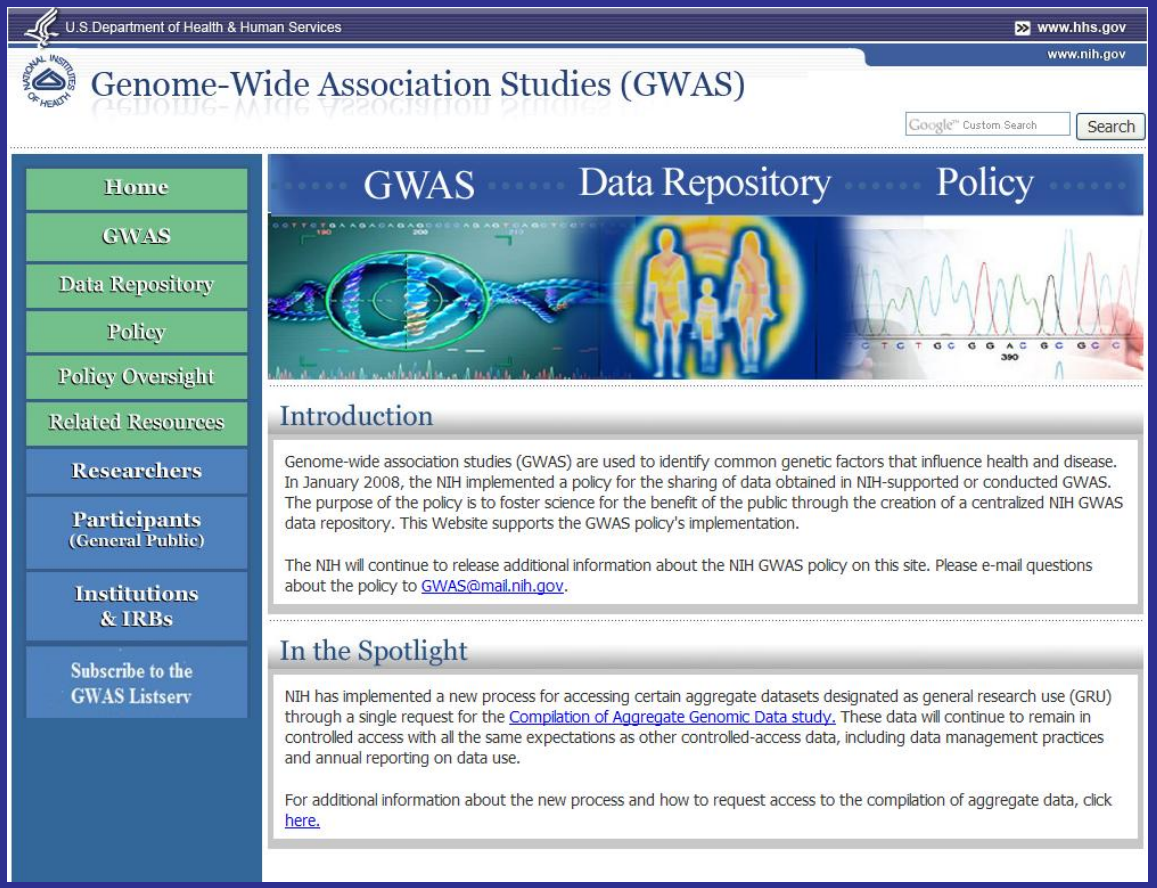
Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

Background

The NIH is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease. For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood



Policy Announced: August 28, 2007
Effective Date: January 25, 2008

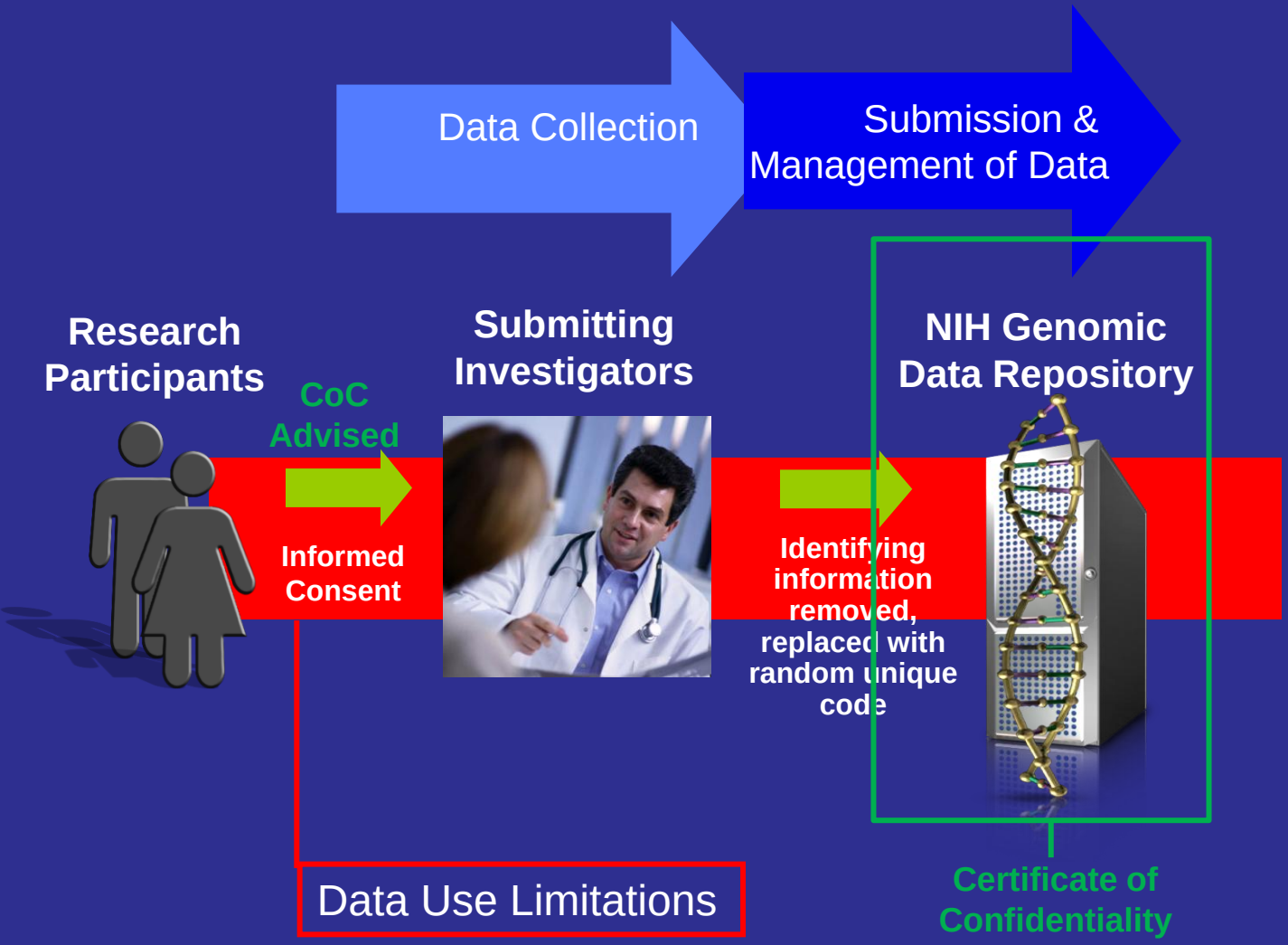
GWAS Homepage: http://gwas.nih.gov/

Guiding Principle for NIH Policies

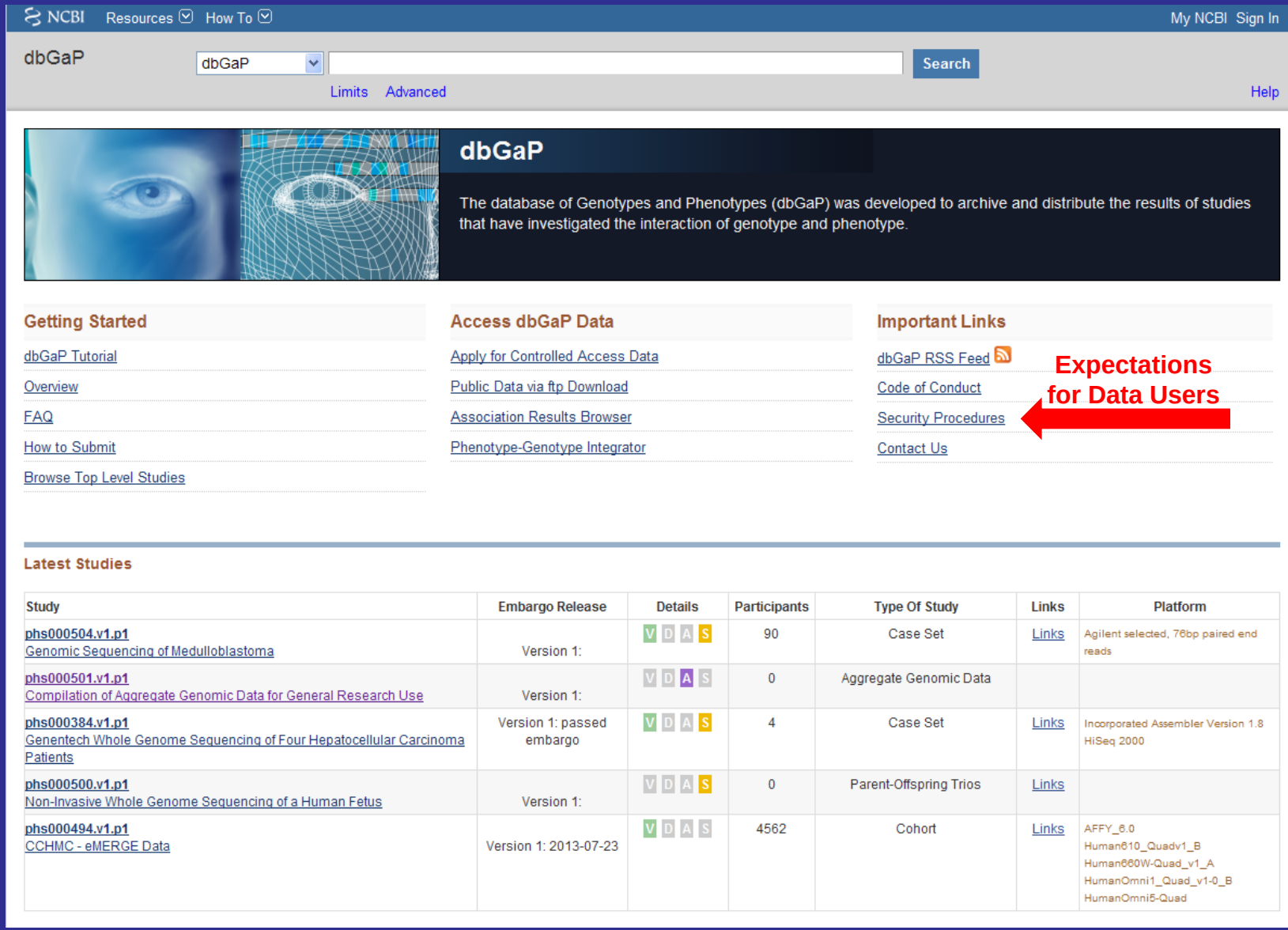
The greatest public benefit will be realized if data from genomic studies are made available, under terms and conditions consistent with the informed consent provided by individual participants, in a timely manner to the largest possible number of investigators.

- Respect for Participants
- Data Sharing
- Freedom to Operate

NIH Data Management Overview



IT Security Measures



NIH Data Management Overview

Data Collection

Submission & Management of Data

Distribution & Secondary Use of Data

Research Participants

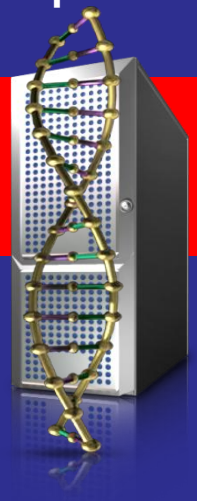
Submitting Investigators

NIH Genomic Data Repository

Recipient Investigators

Informed Consent

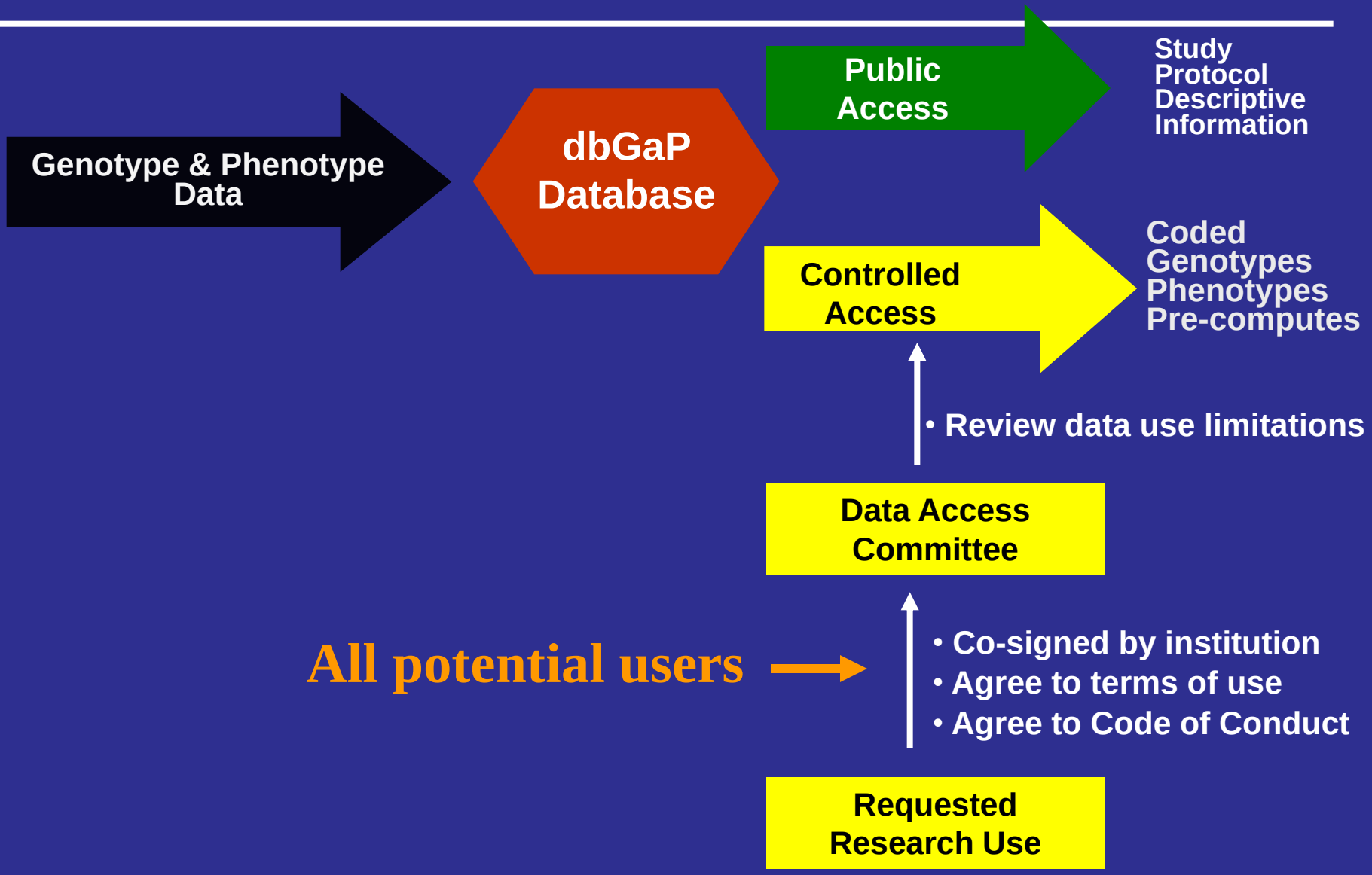
Identifying information removed, replaced with random unique code



Data Access Request by Consent Groups

Data Use Limitations

Data Access


Genotype & Phenotype Data
dbGaP Database
Public Access
Study Protocol Descriptive Information
Controlled Access
Coded Genotypes Phenotypes Pre-computes
• Review data use limitations
Data Access Committee
All potential users
• Co-signed by institution
• Agree to terms of use
• Agree to Code of Conduct
Requested Research Use

Data Use Certification Agreement

Terms and conditions include that requesters will:

- be responsible for compliance with federal, state, and local policies
- only use the data for the specified research use
- not identify study participants
- not transfer data beyond approved users
- immediately notify the DAC if a security breach occurs
- submit brief annual updates on research and publications
- be identified as an Approved User within the dbGaP
- acknowledge other GWAS policies
- abide by Genomic Data User Code of Conduct

Public Disclosure under FOIA

- dbGaP GWAS data will be coded and deidentified.
- Policy concern remains that the extensive genomic data in dbGaP is intrinsically unique.
- NIH intends to deny FOIA requests for individual-level genomic data.
- ACD Working Group recommended seeking a legislative exception for genomic data

Compelled Disclosure

- Law enforcement and other judicial requests for data are handled under different procedures than FOIA requests.
- Standard protection is provided through the Secretary's "301(d)" authority *(aka Certificates of Confidentiality).*
  - Certificates are issued for a single project.
  - Submitting Investigators are encouraged to consider requesting a Certificate of Confidentiality.
  - dbGaP has received a Certificate.

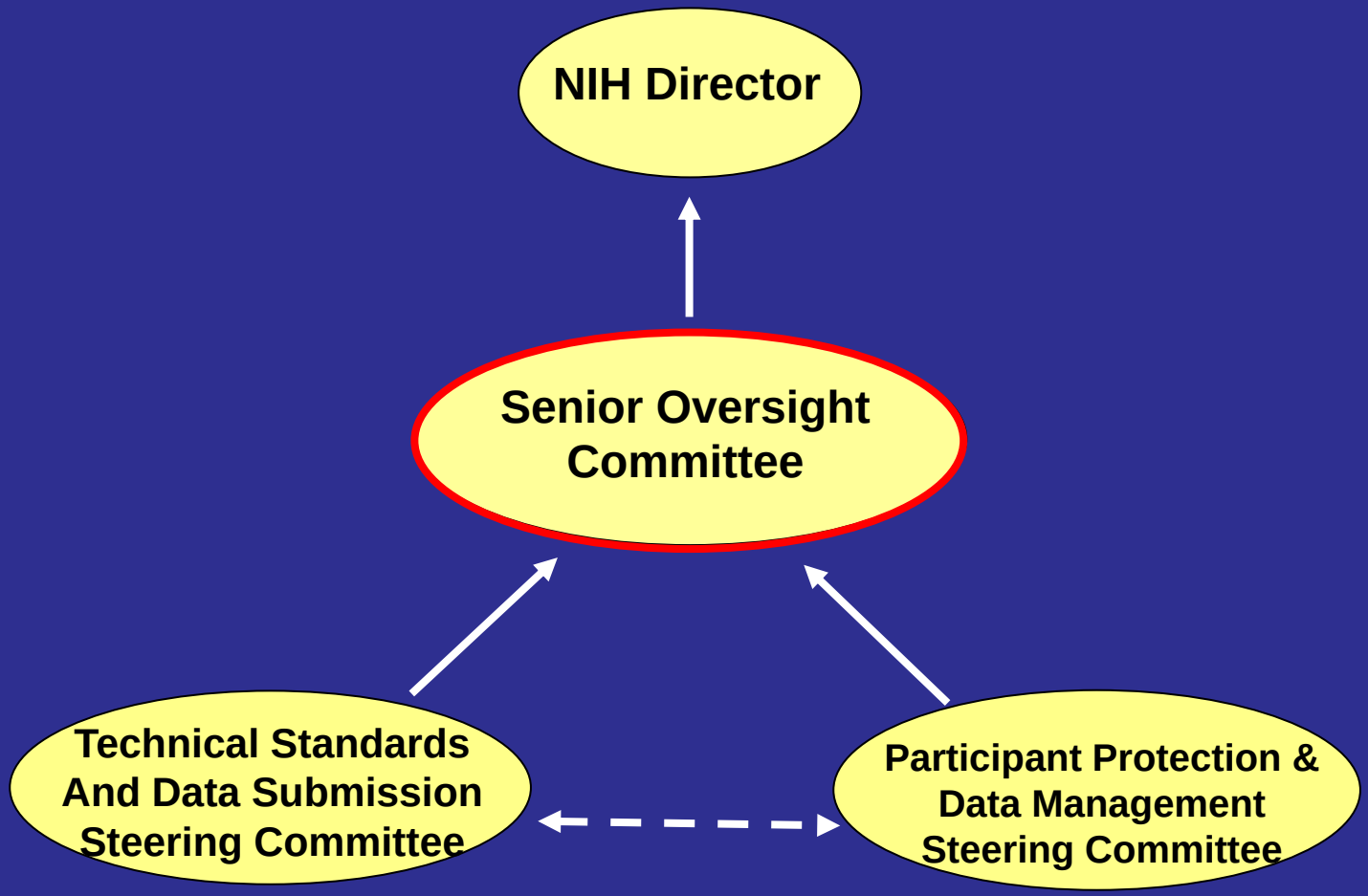
Exceptions to Data Deposition

- Policy notes that there will be cases where data deposition may not be appropriate
- Requests for exceptions are to come in within the grant Data Sharing Plan
- To date: 7 requests granted
  - Limited consent
  - Legal restrictions
  - Localized geographic representation

Data Use Experience

- Over 300 available studies (more in pipeline)
- Over 500 organizations across the research community and from 36 countries with Approved Users
- Number of active projects continues to increase substantially each year
- Estimates indicate >450 publications per year
- 3539 approved projects since dbGaP launch and there have been 16 Data Management Incidents

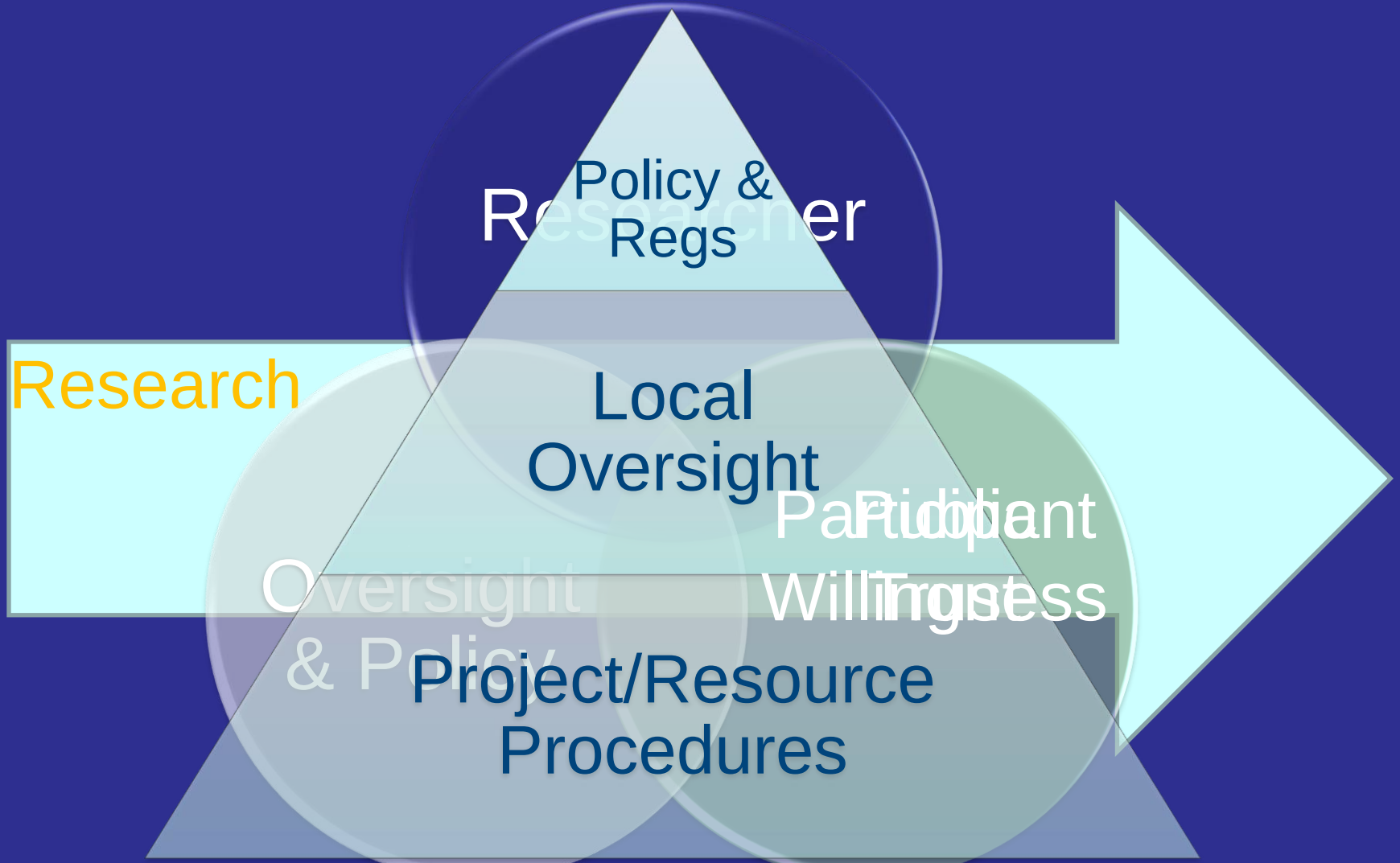
Stewardship & Oversight



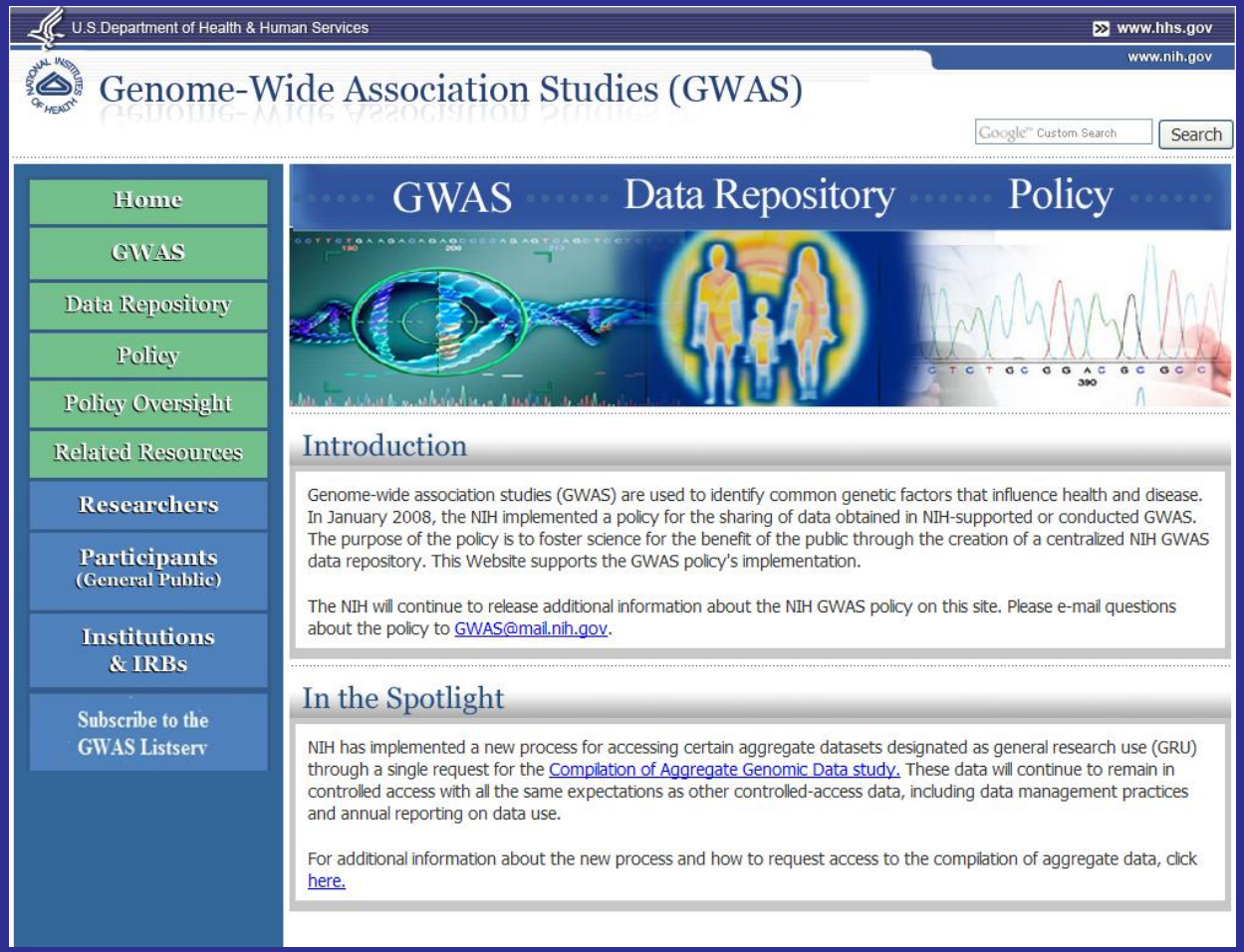
Fast Forward to 2012

- The Power of Statistics
- Accessibility of Technology
- Participant-focused Research
- Participant Directions
- Media Coverage
- Policy Developments

Systems of Trust Oversight



For more Information & Updates



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